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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/563,566 | 02/23/2006 | Brian A. Whittle | 187287/US | 3673 |

67374 7590 06/06/2008

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| EXAMINER | |
|---|---|
| COLLINS, MICHAEL | |
| ART UNIT | PAPER NUMBER |
| 3651 | |
| MAIL DATE | DELIVERY MODE |
| 06/06/2008 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/563,566 | WHITTLE ET AL. | |
| | Examiner | Art Unit | |
| | MICHAEL K. COLLINS | 3651 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *01 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *23-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-38* is/are rejected.

7)☒ Claim(s) *17* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 August 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/31/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Drawings*

1. The drawings were received on 8/31/2007. These drawings are acceptable.

### *Claim Objections*

2. Claim 38 is objected to because of the following informalities: "dosage unites" should be "dosage units". Appropriate correction is required.

### *Response to Arguments*

3. Applicant's arguments with respect to claims 23-38 have been considered but are moot in view of the new ground(s) of rejection.

### *Claim Rejections - 35 USC § 102*

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 23-25 and 36-38 are rejected under 35 U.S.C. 102(e) as being anticipated by Howard (USP 6,865,444).

Regarding claim 23, Howard discloses a dispenser comprising a reservoir (14) containing a formulation for a controlled drug or drug of abuse (see column 6 lines 14-18) presented in a format such that:

- (a) a patient's access to the formulation is controlled (see column 1 lines 50-65); and
- (b) the patient's access to the formulation is monitored in real time (see column 3 lines 35-56);
- such that the control over the patient's usage of the formulation does not require the supervision of a healthcare professional at the time of administration (see column 4 lines 4-43).

Regarding claim 24, Howard discloses the dispenser as claimed in claim 23, wherein the controlled drug or drug of abuse is a class A drug in a non-intravenous formulation, as defined by The Misuse of Drugs Act 1971 (see column 6 lines 14-34).

Regarding claim 25, Howard discloses the dispenser as claimed in claim 23, wherein the controlled drug or drug of abuse is an opioid.

Regarding claim 36, Howard discloses the dispenser as claimed in claim 23, wherein a number of doses of the formulation are stored within the reservoir to be supplied to the patient (see Figure 3).

Regarding claim 37, Howard discloses a dispenser comprising a reservoir (14) containing a plurality of dosage units each of which comprise a formulation of a controlled drug or drug of abuse (see column 6 lines 14-18), said dosage units being contained in a tamper-evident manner (see column 4 lines 34-38) such that:

- (a) a patient's access to the dosage units is controlled (see column 1 lines 50-54); and
- (b) the patient's access to the dosage units is monitored in real time (see column 3 lines 35-36);
- such that the control over the patient's usage of the formulation does not require the supervision of a healthcare professional at the time of administration (see column 4 lines 4-43).

Regarding claim 38, Howard discloses the dispenser of claim 37, wherein more than 1 day's supply of dosage unites are contained in the dispenser (see Figure 3).

### *Claim Rejections - 35 USC § 103*

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 26-27 and 29-30 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Howard (USP 6,865,444).

Regarding claim 26, Howard discloses the dispenser as claimed in claim 25, wherein the opioid is methadone or a pharmaceutically acceptable salt or derivation thereof. Yet, "Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim." Ex parte Thibault,164 USPQ 666, 667 (Bd. App. 1969). Furthermore, "[i]nclusion of material or article worked upon by a structure being claimed does not impart patentability to the claims." In re Young, 75 F.2d *>996<, 25 USPQ 69 (CCPA 1935) (as restated in In re Otto, 312 F.2d 937, 136 USPQ 458, 459 (CCPA 1963)). [SEE MPEP 2115].

Regarding claim 27, Howard discloses the dispenser as claimed in claim 26. However, he does not specifically disclose a dispenser wherein the opioid is methadone hydrochloride. Yet, "Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim." Ex parte Thibault,164 USPQ 666, 667 (Bd. App. 1969). Furthermore, "[i]nclusion of material or article worked upon by a structure being claimed does not impart patentability to the claims." In re Young, 75 F.2d *>996<, 25 USPQ 69 (CCPA 1935) (as restated in In re Otto, 312 F.2d 937, 136 USPQ 458, 459 (CCPA 1963)). [SEE MPEP 2115].

Regarding claim 29, Howard discloses the dispenser as claimed in claim 25. However, he does not specifically disclose a dispenser wherein the opioid is diamorphine or a pharmaceutically acceptable salt or derivative thereof. Yet,

"Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim." Ex parte Thibault,164 USPQ 666, 667 (Bd. App. 1969). Furthermore, "[i]nclusion of material or article worked upon by a structure being claimed does not impart patentability to the claims." In re Young, 75 F.2d *>996<, 25 USPQ 69 (CCPA 1935) (as restated in In re Otto, 312 F.2d 937, 136 USPQ 458, 459 (CCPA 1963)). [SEE MPEP 2115].

Regarding claim 30, Howard discloses the dispenser as claimed in claim 29. However, he does not specifically disclose a dispenser wherein the opioid is diamorphine hydrochloride. Yet, "Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim." Ex parte Thibault,164 USPQ 666, 667 (Bd. App. 1969). Furthermore, "[i]nclusion of material or article worked upon by a structure being claimed does not impart patentability to the claims." In re Young, 75 F.2d *>996<, 25 USPQ 69 (CCPA 1935) (as restated in In re Otto, 312 F.2d 937, 136 USPQ 458, 459 (CCPA 1963)). [SEE MPEP 2115].

9. Claims 28 and 31-35 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hickle et al. (USPGPUB 2003/0074223 A1).

Regarding claim 28, Hickle et al. disclose the dispenser as claimed in claim 26, wherein the opioid is for oral delivery.

Regarding claim 31, Hickle et al. disclose the dispenser as claimed in claim 29, wherein the diamorphine is dry and suitable for nasal delivery upon mixing with an

aqueous solution.

Regarding claim 32, Hickle et al. disclose the dispenser as claimed in claim 31, wherein the formulation for nasal delivery further comprises a solubility enhancer.

Regarding claim 33, Hickle et al. disclose the dispenser as claimed in claim 32, wherein the solubility enhancer is one or more of caffeine, sodium benzoate and sodium salicylate.

Regarding claim 34, Hickle et al. disclose the dispenser as claimed in claim 32, wherein the solubility enhancer comprises caffeine, sodium benzoate, sodium salicylate, or a combination thereof.

Regarding claim 35, Hickle et al. disclose the dispenser as claimed in claim 31, wherein the formulation for nasal delivery is a freeze-dried formulation.

## ***Conclusion***

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL K. COLLINS whose telephone number is (571)272-8970. The examiner can normally be reached on 8:30 am - 5:00 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gene O. Crawford can be reached on (571) 272-6911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

M.K.C.
6/03/2008

/Gene Crawford/
Supervisory Patent Examiner, Art Unit 3651